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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/088,766	06/20/2002	Martinas Kuslys	112843-043	2286

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EXAMINER
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HINES, JANA A

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 05/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/088,766	Applicant(s) KUSLYS ET AL.	
	Examiner Ja-Na Hines	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 10 January 2005.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-10 and 12-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10 and 12-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>1/10/05</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Amendment Entry***

1. The amendment filed January 10, 2005 has been entered. The examiner acknowledges the amendments to the specification. Claims 1, 3, 6-10, 12-15, and 17-20 have been amended. Claim 11 has been cancelled. Claims 1-10 and 12-20 are under consideration in this office action.

### ***Specification***

2. The abstract of the disclosure does not commence on a separate sheet in accordance with 37 CFR 1.52(b)(4). A new abstract of the disclosure is required and must be presented on a separate sheet, apart from any other text. It appears that applicant has attempted to add a new paragraph on page 9 at line 26 of the instant specification, however it is unclear if applicant is attempting to add this paragraph to the body of the specification or if applicant intends this addition to be the abstract. Therefore clarification is required.

It is noted that a brief abstract of the technical disclosure in the specification must commence on a separate sheet, preferably following the claims, under the heading "Abstract" or "Abstract of the Disclosure." The sheet or sheets presenting the abstract may not include other parts of the application or other material. The abstract in an application filed under 35 U.S.C. 111 may not exceed 150 words in length. The purpose of the abstract is to enable the United States Patent and Trademark Office and the public generally to determine quickly from a cursory inspection the nature and gist of the technical disclosure.

***Withdrawal of Rejections***

3. The rejection of claims 1-10 and 12-20 under 35 U.S.C. 112, second paragraph, has been withdrawn in view of applicants' amendments.

***Response to Arguments***

4. Applicants' arguments filed January 10, 2005 have been fully considered but they are not persuasive. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***Double Patenting***

5. The rejection of claims 1-10 and 12-20 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 and 12-20 of U.S. Patent No.6,777,391 is maintained for reasons already of record.

Applicants' assert that they believe that this rejection is improper with respect to the claims. However even though the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to a composition comprising a whey component which is an acid whey protein or sweet whey from which caseino-glyco-macropeptide has been removed; casein protein, free arginine, free histidine, free tryptophan, tryptophan based milk protein and mixtures thereof. It is noted that the claims recite "comprising" and this transitional term is inclusive or open-ended and does not exclude additional, unrecited elements or method steps. Therefore, even

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though the level of milk protein has been recited in the instant claims, the claims are still not patentably distinct. Instant claim 10 is drawn to a method of producing an infant formula comprising the same steps as claim 17 of US Patent 6,777,391. Therefore these method steps are not patentable distinct. Instant claim 20 is drawn to a method of providing nutrition to an infant comprising the same steps as claim 19 of US Patent 6,777,391. Although the conflicting claims are not identical, they are not patentably distinct from each other because even through the preamble of the claims are slightly different, the steps within the method recite the same method steps as those instantly claimed. Finally, claims 13-19 of the instant application are drawn to an infant formula comprising the exact same components as the infant formula claimed within the patent, see claims 13-16 and 20. Therefore, because the formulas are not patentably distinct, the rejection is maintained. Thus, despite applicants' belief that the rejection should be withdrawn, the rejection is maintained because even though the conflicting claims are not identical, they are not patentably distinct from each other.

***Claim Rejections - 35 USC § 103***

6. The rejection of claims 1-10 and 12-20 under 35 U.S.C. 103(a) as being unpatentable over JP-002158762 is maintained for reasons already of record. The rejection was on the grounds that JP-002158762 teach compositions and formula comprising whey protein, wherein the whey protein is acid or sweet whey from which caseino-glyco-macropeptide has been removed; casein protein, free

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arginine, free histidine, milk protein that has a level of 5% or more amino acids as tryptophan; free tryptophan, and mixtures thereof. JP-002158762 also teaches methods of production comprising blending the recited components and methods of treating malnutrition or providing nutrition whose only active step is administering the composition. Finally, no more than routine skill is involved in adjusting the amount of the components of the claimed composition or process in order to achieve the results taught in the prior art.

Applicants' believe that the prior art is distinguishable because the prior art provides a preparation of a nutritive composition that may be used as infant food particularly suitable for the treatment of some disease. The MPEP section 2123 teaches that patents are relevant as prior art for all they contain, "The use of patents as references is not limited to what the patentees describe as their own inventions or to the problems with which they are concerned. They are part of the literature of the art, relevant for all they contain." *In re Heck*, 699 F.2d 1331, 1332-33, 216 USPQ 1038, 1039 (Fed. Cir. 1983) (quoting *In re Lemelson*, 397 F.2d 1006, 1009, 158 USPQ 275, 277 (CCPA 1968)). A reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill in the art, including nonpreferred embodiments. *Merck & Co. v. Biocraft Laboratories*, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989). Therefore applicant's argument is not persuasive especially when considering that the patent discloses compositions comprising the same instantly claimed components, thus it meets the limitations of the claims.

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The fact that the patent discloses that the nutritive composition may be used as infant food particularly suitable for the treatment of some disease does not distinguish the instant claims over this art. The disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. *In re Susi*, 440 F.2d 442, 169 USPQ 423 (CCPA 1971). "A known or obvious composition does not become patentable simply because it has been described as somewhat inferior to some other product for the same use." *In re Gurley*, 27 F.3d 551, 554, 31 USPQ2d 1130, 1132 (Fed. Cir. 1994). Therefore contrary to applicants' argument, the prior art does not teach away from the instant claims, since the prior art teaches compositions with exactly the same components and additional uses are irrelevant.

Applicants' also state that the composition includes additional amino acids and minerals not recited by the instant claims. However the instant claims recite "comprising" and this transitional term is synonymous with "including," "containing," or "characterized by," and is inclusive or open-ended and does not exclude additional, unrecited elements such as different amino acids or minerals or method steps. Therefore applicants' argument is not persuasive.

Applicants' assert that the cited art does not suggest to remove CGMP from whey in contrast to the claims. However this argument is unpersuasive since the claims do not require that CGMP be removed. Rather the claims recite alternative "or" language; therefore as long as the art teaches that the whey protein is an acid or that the whey protein is sweet whey from which caseino-

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glyco-macropeptide has been removed it meets the limitations of the claims. The patent refers to whey powder which is well known in the art to be the dry form of the whey protein that is an acid, thus the patent teaches the instantly claimed limitations.

In response to applicants' argument that the instantly claimed composition provides a reduced threonine and can provide a balanced amount of all essential amino acids to an infant, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 370 F.2d 576, 152 USPQ 235 (CCPA 1967). In the instant case the composition of JP-002158762 meets the instantly claimed limitations since there are no structural differences. Therefore applicants' arguments are not persuasive and the rejection is maintained.

### ***Conclusion***

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory



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action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 571-272-0859. The examiner can normally be reached on Monday-Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 571-272-0864. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ja-Na Hines  
April 27, 2005

LSB  
LYNETTE R. F. SMITH  
SUPERVISORY PATENT EXAMINER  
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